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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,315	10/19/2007	Kai Wucherpfennig	PEPT-P01-006	9509

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EXAMINER	
DIBRINO, MARIANNE NMN	
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1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,315	WUCHERPFENNIG ET AL.	
	Examiner	Art Unit	
	MARIANNE DIBRINO	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,7,9,18,23-26,31,40-42,47,68,74,75 and 83-86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,5,7,9,18,23-26,31,40-42,47,68,74,75,83-86* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 10/19/07 is acknowledged and has been entered.

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, Applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1, 18, 23-26 and 31, drawn to a semi-random copolymer and composition thereof, said copolymer having the structural limitations recited in instant base claims 1 and 24 and their dependent claims.

II. Claims 5, 7 and 9, drawn to a random copolymer composition having the structural limitations recited in instant base claim 5.

III. Claims 40 and 47, drawn to a method for treating an autoimmune disease comprising administering to a subject a copolymer composition that comprises one or more random sequence copolymers that binds to an HLA-DQ molecule associated with the autoimmune disease.

IV. Claims 41*, 42, 68, 74 and 75, drawn to a method for treating an autoimmune disease comprising administering to a subject a copolymer composition that comprises the semi-random copolymer recited in instant claim 41, and drawn to a method for prophylactically treating a subject at risk of or having pre-conditions for developing an

autoimmune disease, comprising administering the copolymer of claim 18 (which is the semi-random copolymer recited in claim 1 from which claim 18 depends).

***It is pointed out to Applicant that "semi-random sequence copolymers" recited in dependent claim 41 lacks antecedent basis in base claim 40, as base claim 40 recites "random sequence copolymers."**

V. Claims 83-86, drawn to a method for identifying a copolymer that is therapeutically effective to treat an HLA-DQ mediated autoimmune disease.

3. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claim 40 of the instant application does not provide a technical feature that is distinguished over the prior art, as evidenced by Fridkis-Hareli *et al* (J. Clin. Invest. 2002, 109: 1635-1643, IDS reference) in view of Das *et al* (Human Immunology, 2000, 61(3): 279-289).

Fridkis-Hareli *et al* teach that random copolymers VEAK and Cop 1 (YEAK) are equally effective in partially reducing the severity of EAE (an MS-like autoimmune disease in mice) induced by PLP 139-151 in I-A^s mice (*i.e.*, these mice only express the I-A^s class II MHC molecule), while FEAK completely prevented the appearance of the disease (especially paragraph section "(c)" at column 1 on page 1638). Fridkis-Hareli *et al* also teach efficacy of treatment with YFAK. Fridkis-Hareli *et al* further teach that I-A^s is the homologue of human HLA-DQ protein. Fridkis-Hareli *et al* teach that the copolymers bind to I-A^s (especially second full paragraph at column 1 on page 1641).

Das *et al* teach that complementation between specific HLA-DR and HLA-DQ genes in transgenic mice determines susceptibility to EAE. Das *et al* further teach that transgenic mice expressing HLA-DR3 and HLA-DQ8 develop severe inflammatory lesions and clinical disease (EAE) in response to immunization with mouse myelin (especially abstract).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have treated EAE in the double transgenic mice taught by Das *et al* with the copolymer composition FEAK, VEAK or YFAK taught by Fridkis-Hareli *et al*.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to treat EAE, especially in light of the teaching of Fridkis-Hareli *et al* that I-A^s is the homologue of human HLA-DQ protein.

Therefore, because claim 40 does not provide a special technical feature, the instant invention lacks an inventive step and therefore lacks Unity of Invention

4. The Examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

5. This application contains claims directed to or generic to the following patentably distinct species:

Of Invention I: a copolymer composition comprising

- a specific core amino acid sequence, for example, that at [00203] of the specification, and
- that further comprises specific other amino acid residues from the amino acid residues recited in instant base claim 1, for example, alanine and valine, and
- that binds to a specific HLA-DQ allele product such as one of the HLA-DQ molecules disclosed in the specification that is associated with a specific autoimmune disease, such as for example, .one of the disease conditions such as diabetes mellitus recited in instant claim 18, or other species disclosed in the instant specification. Note that an "unwanted immune response" is not an ultimate species, and
- *If* the pharmaceutical composition thereof further comprises an additional therapeutically active agent, Applicant is required to elect a specific species of agent such as for example, "insulin" disclosed in the instant specification.

Of Invention II:

- a specific copolymer composition comprising specific amino acid residues, such as for example, DGLE recited in instant claim 5, part 6, and
- wherein the molar output ratio of amino acid residues is, for example, D:G:L:E of 1:25:15:5 such as recited in instant claim 7, part 3 and in instant claim 9 at part 2.

Of Invention III:

- a copolymer composition comprising a specific core amino acid sequence, for example, that at [00203] of the specification, and
- that binds to a specific HLA-DQ allele product such as one of the HLA-DQ molecules disclosed in the specification that is associated with a specific autoimmune disease, such as for example, one of the disease conditions such as diabetes mellitus recited in instant claim 47, or other species disclosed in the instant specification. Note that an "unwanted immune response" is not an ultimate species.

Of Invention IV:

- a specific core amino acid sequence, for example, that at [00203] of the specification, and
- that further comprises specific other amino acid residues from the amino acid residues recited in instant base claim 1 (claim 18 depends on claim 1, and the method recited in instant claim 68 administers the copolymer of claim 18), for example, alanine and valine, and glutamic acid for the anchor residue, as also recited in instant claim 41, and
- that binds to a specific HLA-DQ allele product such as one of the HLA-DQ molecules disclosed in the specification that is associated with a specific autoimmune disease, such as for example, .one of the disease conditions such as diabetes mellitus recited in instant claim 68, or other species disclosed in the instant specification. Note that an "unwanted immune response" is not an ultimate species, and
- *If* the method also further comprises administering a second therapeutically active agent, Applicant is required to elect a specific species of agent such as for example, "insulin" disclosed in the instant specification.

Of Invention V:

- a specific random copolymer comprising specific amino acid residues such as for example, DASE recited in instant claim 83, and
- a specific autoantigenic peptide such as human GAD 206-220, and
- a specific HLA-DQ molecule, such as for example, DQA1*03.

The species are independent or distinct because they have different structures that require different searches, in some instances, different sequence searches, and in others, different text searches. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply: where the sequences are semi-random, the sequences have partially defined amino acid sequence with specific anchor residues and specific linear structure which requires different sequence searches. Random copolymers have different compositions that require employing different search queries. HLA class II molecules have different structures and bind peptides or polypeptides with different structures and elicit differently restricted T cell responses. They may also possess different disease associations, all of which require different search queries.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should Applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

7. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ram Shukla, can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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